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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,671	06/27/2003	Michael J. Pugia	MSA-3452	5201
7590 05/17/2006			EXAMINER	
Elizabeth A. Levy Bayer HealthCare LLC Two Edgewater Drive Norwood, MA 02060-4637			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,671

Applicant(s)

PUGIA ET AL.

Examiner

Brian J. Sines

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/3/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

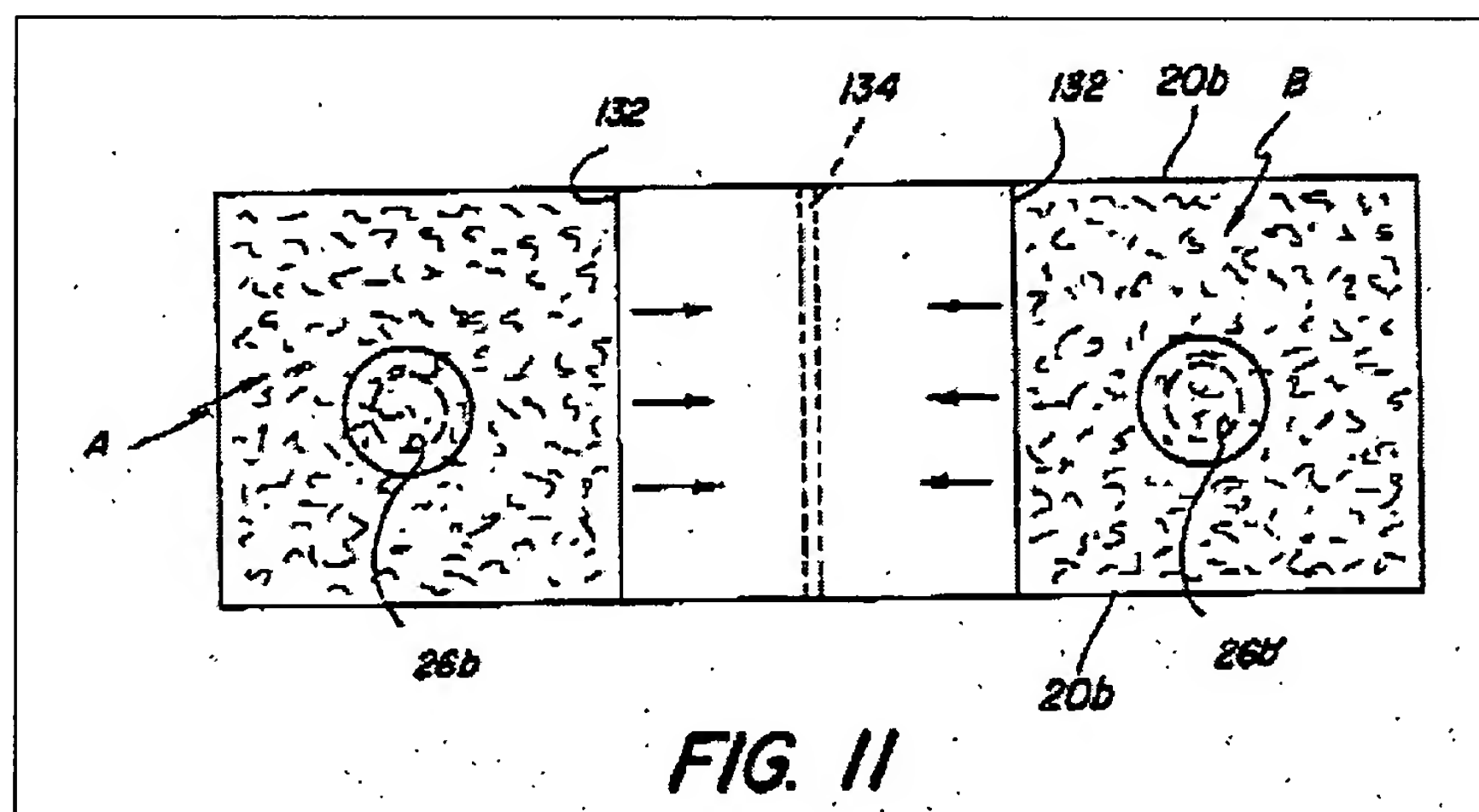
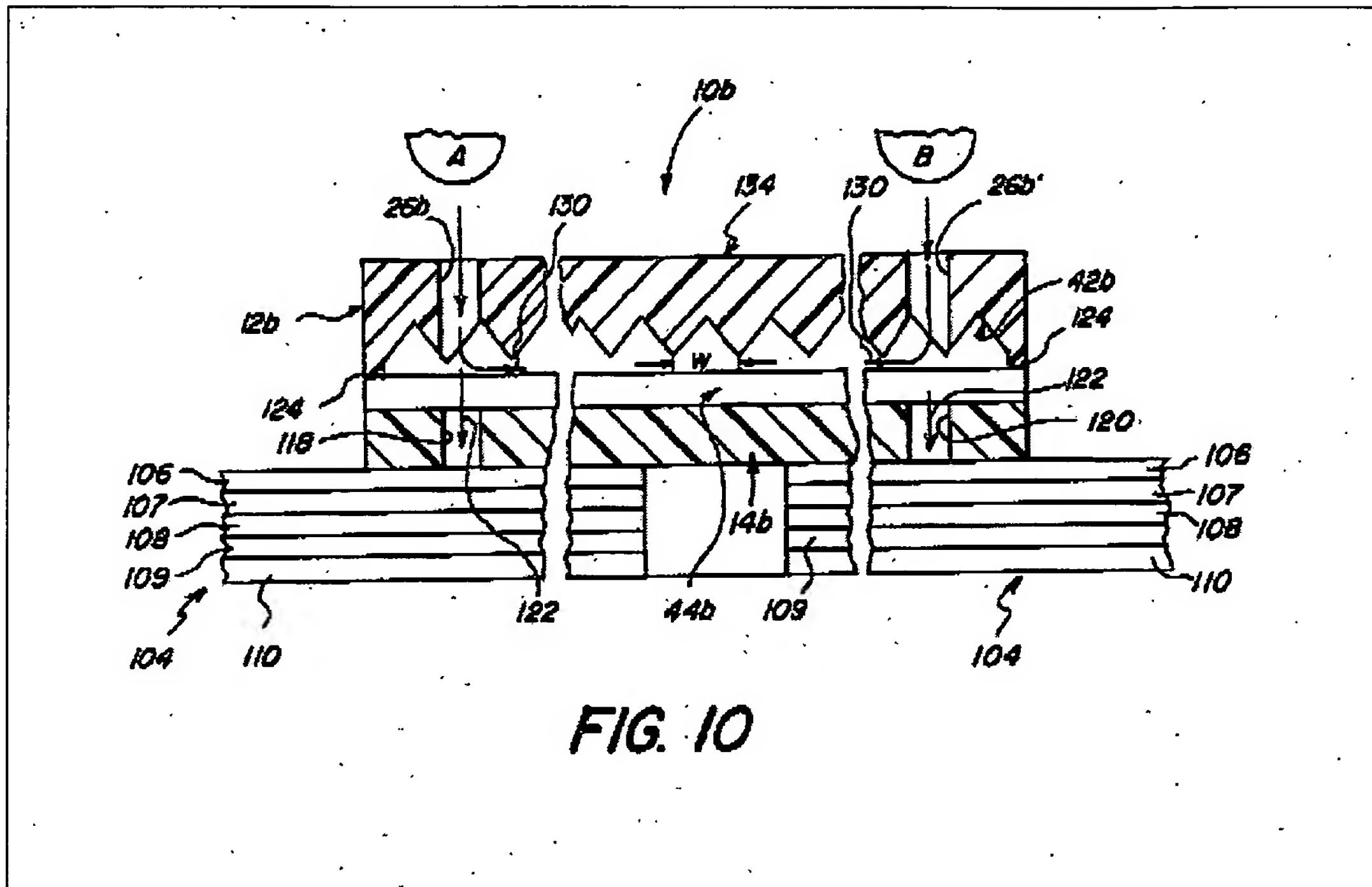
1. Claims 1 – 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Columbus (U.S. Pat. No. 4,233,029).

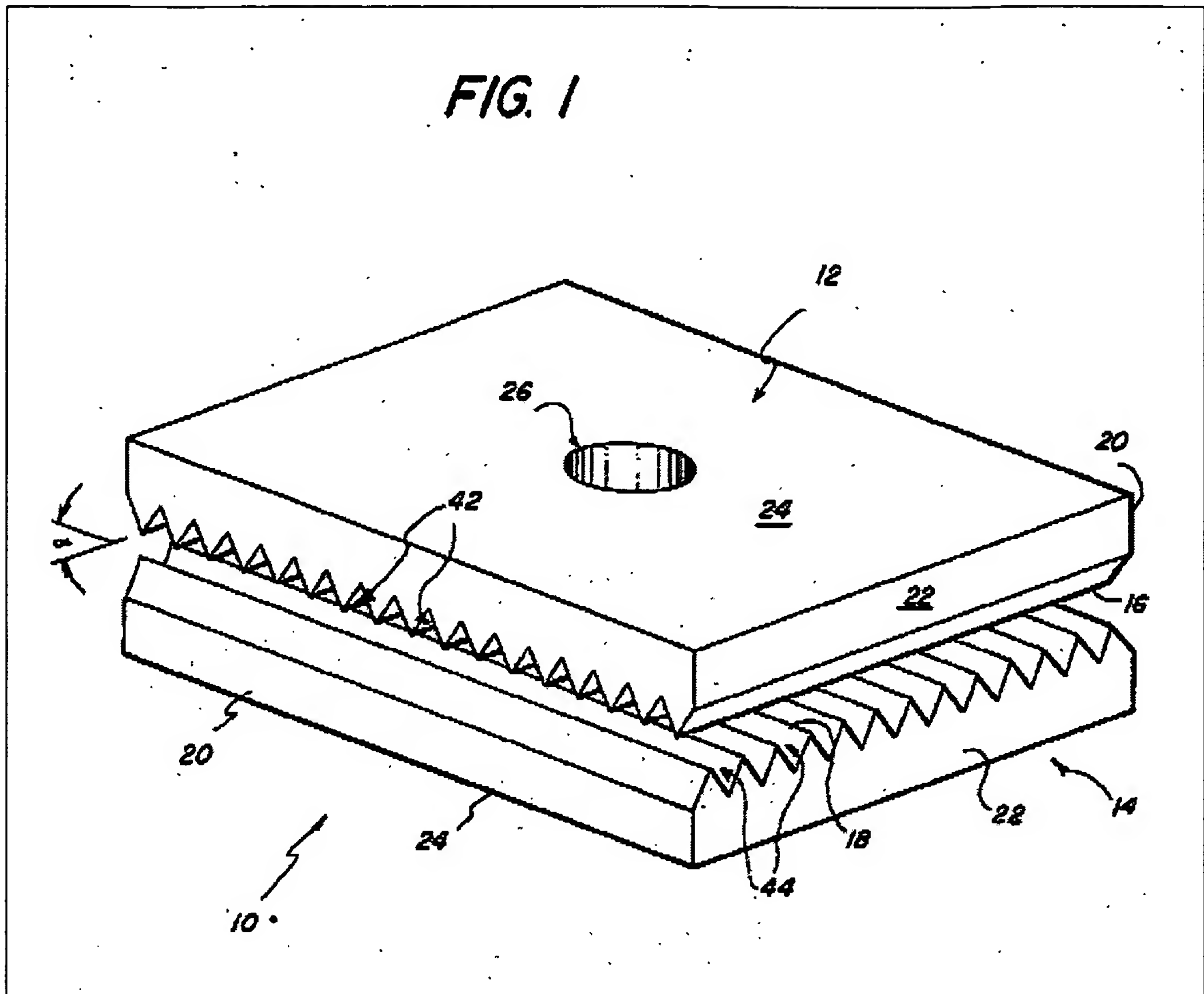
Regarding claims 1 and 2, Columbus '029 teaches a microfluidic apparatus (10) comprising: an inlet port (aperture 26); a capillary passageway (e.g., the sidewalls of the inlet port 26 extending through top member 12) in fluid communication with the inlet port (26); an inlet chamber (e.g., the spacing between interior surfaces 16 & 18) in fluid communication with the capillary passageway, wherein the inlet chamber comprises means (grooves 42 & 44) for uniformly distributing sample fluid across the chamber and displacing air from the chamber; and at least one vent passageway (e.g., the space between members 12 & 14 left exposed at either edge 20 or 22) or additional aperture (e.g., 26b') (see col. 1, line 1 – col. 6, line 60; figures 1 – 3).

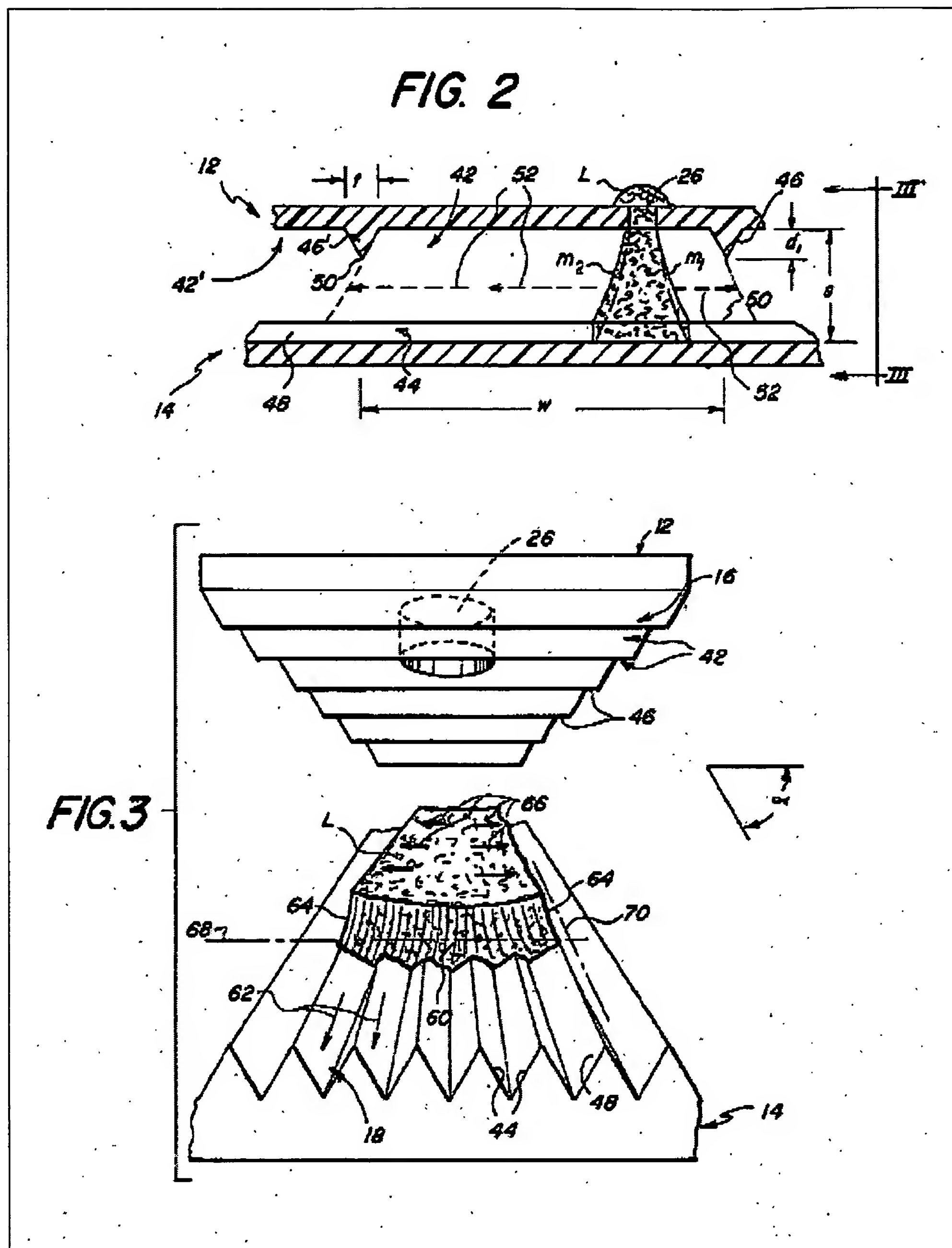
As shown in figures 10 and 11, Columbus '029 further anticipates the incorporation of an enclosed inlet chamber (apertures 26b or 26b') at one side thereof the device.

As shown in figure 10, Columbus '029 anticipates an enclosed passageway. Walls 124 & 144 enclose passageway defined by 44b (see col. 11, lines 1 – 16; fig. 10). Columbus '029

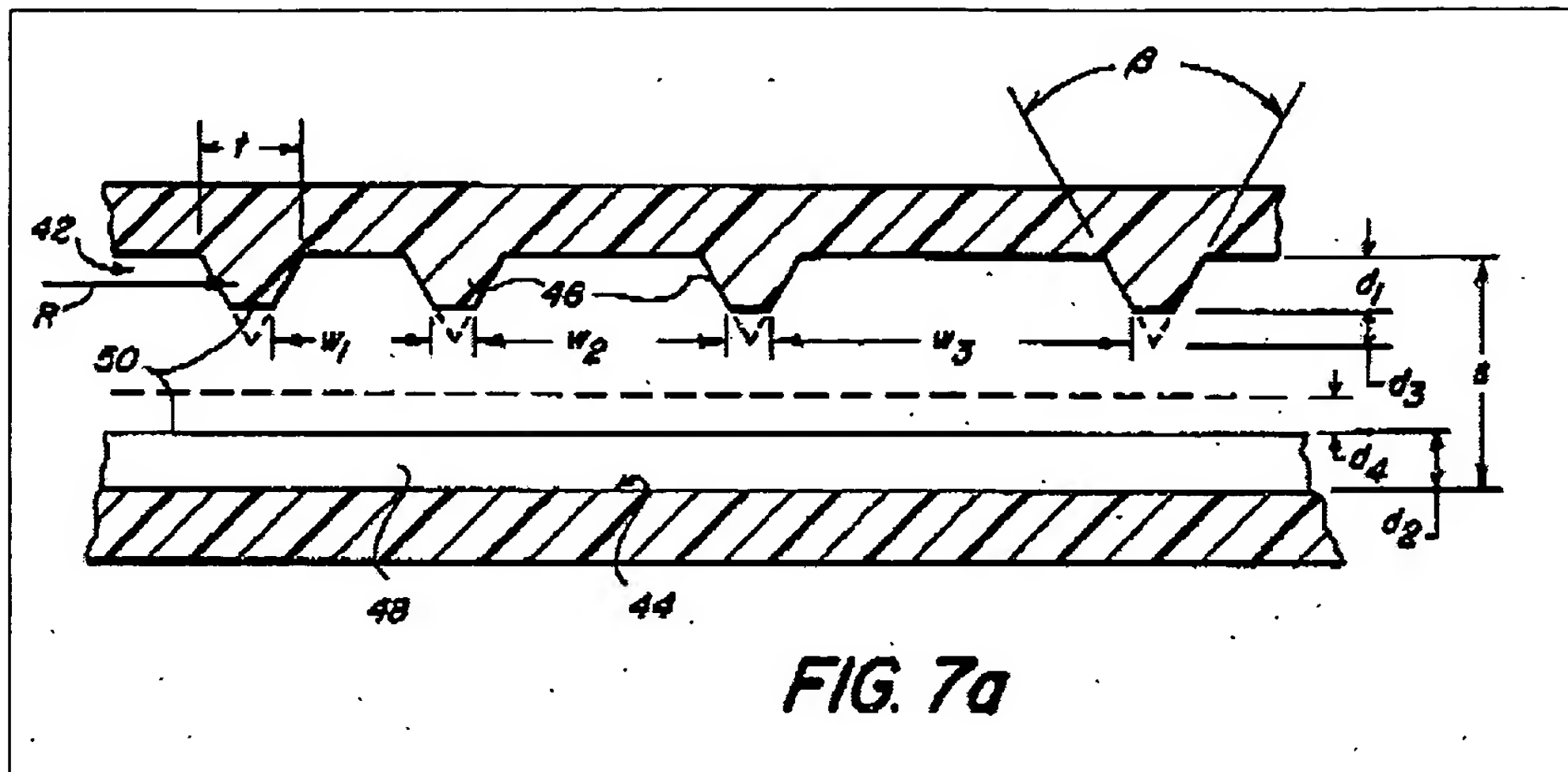
teaches that walls 124 can be additional closure walls, thereby forming an enclosed structure (see col .12, lines 47 – 57).







Regarding claim 3, as shown in figure 7a, Columbus '029 further teaches the incorporation of weir structures (truncated ridges 46) within the apparatus (see col. 8, lines 1 – 51).



Regarding claim 8, the recitation that a reagent is in the inlet chamber is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. The Court has held that “[e]xpressions relating the apparatus contents thereof during an intended use operation are of no significance in determining the patentability of the apparatus claim.” See *Ex parte Thilbault*, 164 USPQ 666, 667 Bd. App. 1969). Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does

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not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

2. Claims 1 – 3 and 8 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Columbus (U.S. Pat. No. 4,618,476).

Regarding claims 1 and 3, as shown in figure 16, Columbus '476 teaches a microfluidic apparatus (multiple test element 400) comprising: an inlet port (inlet aperture 410); a capillary passageway (liquid delivery capillary zones 420 & 430) in fluid communication with the inlet port (410); an inlet chamber (capillary transport zone 30g) in fluid communication with the capillary passageway (420 & 430), wherein the inlet chamber comprises means (e.g., rib structures 40g", which are structurally equivalent to a weir structure) for uniformly distributing sample fluid across the chamber and displacing air from the chamber; and at least one vent passageway (e.g., vent aperture 480) at a side opposite the entry of the capillary passageway (see col. 7, lines 15 – 64; figure 16).

Regarding claim 2, Columbus '476 teach the incorporation of groove or slot structures (142g') within the apparatus. Columbus '476 anticipates an enclosed passageway (e.g., enclosed

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transport zone 30) via the placement of cover top member 16 and bottom member 18 (see col. 3, lines 25 – 50; figures 1, 2 & 5).

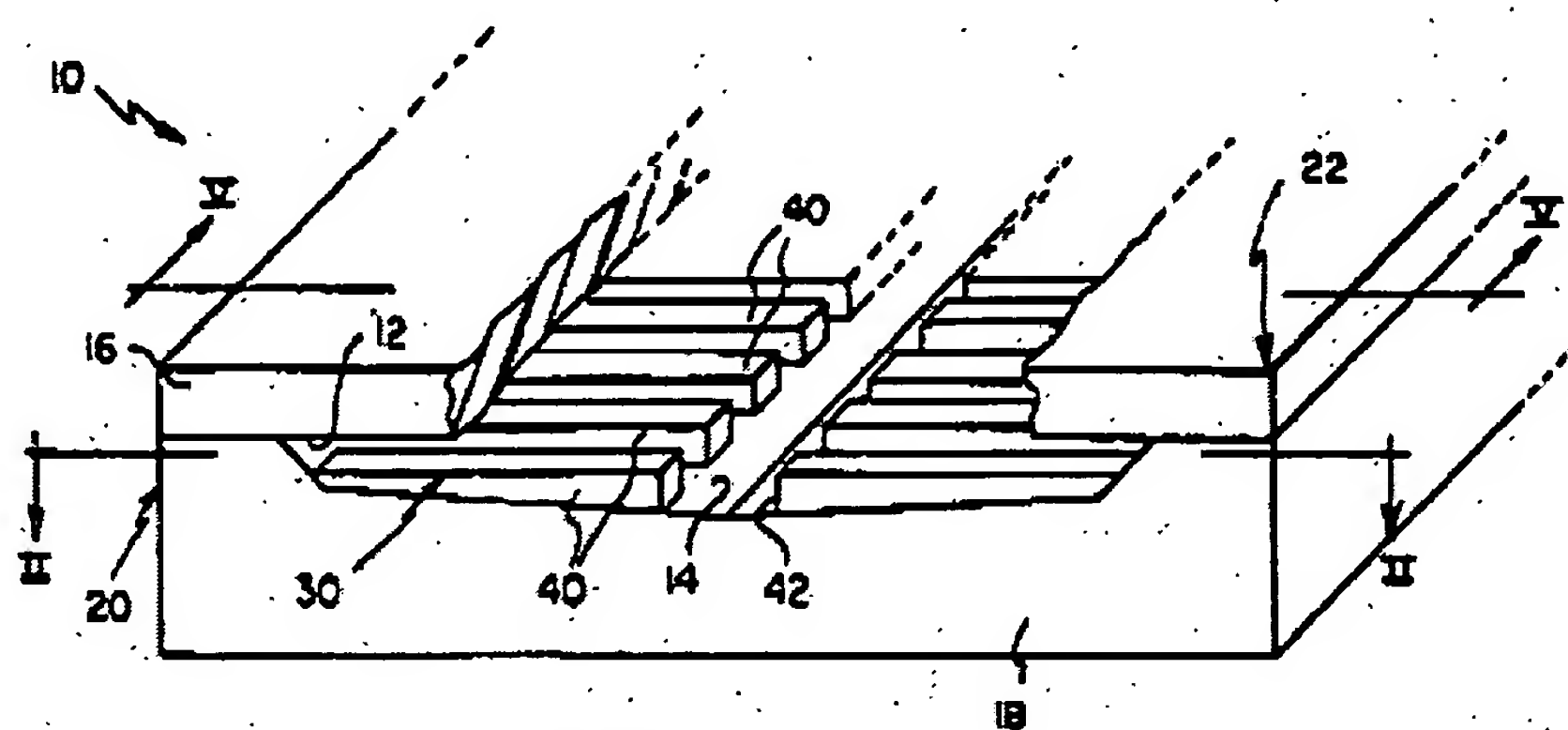


FIG. 1.

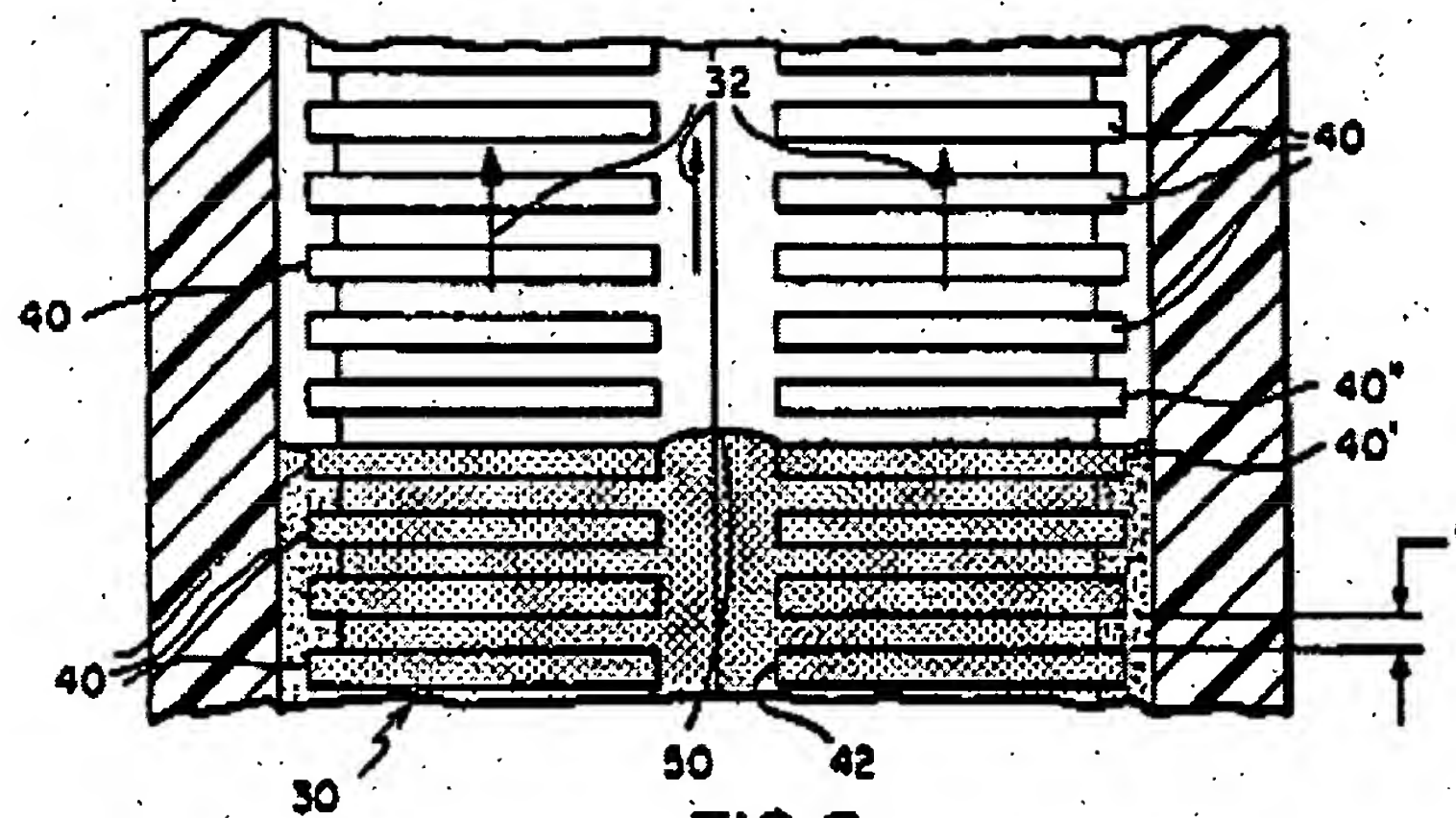


FIG. 2

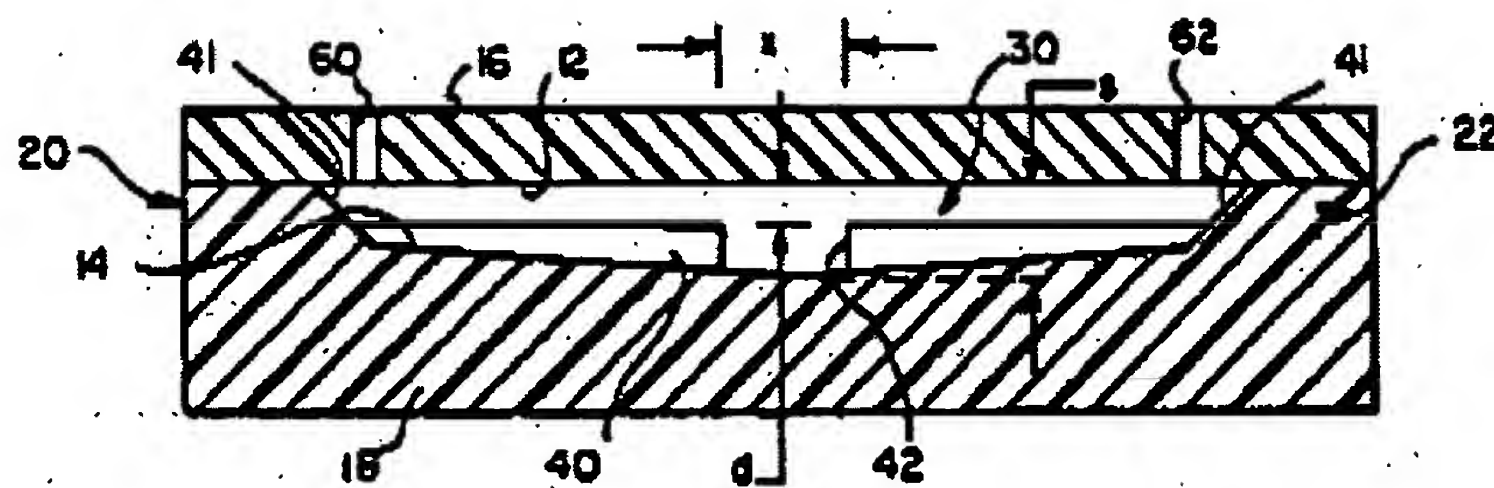
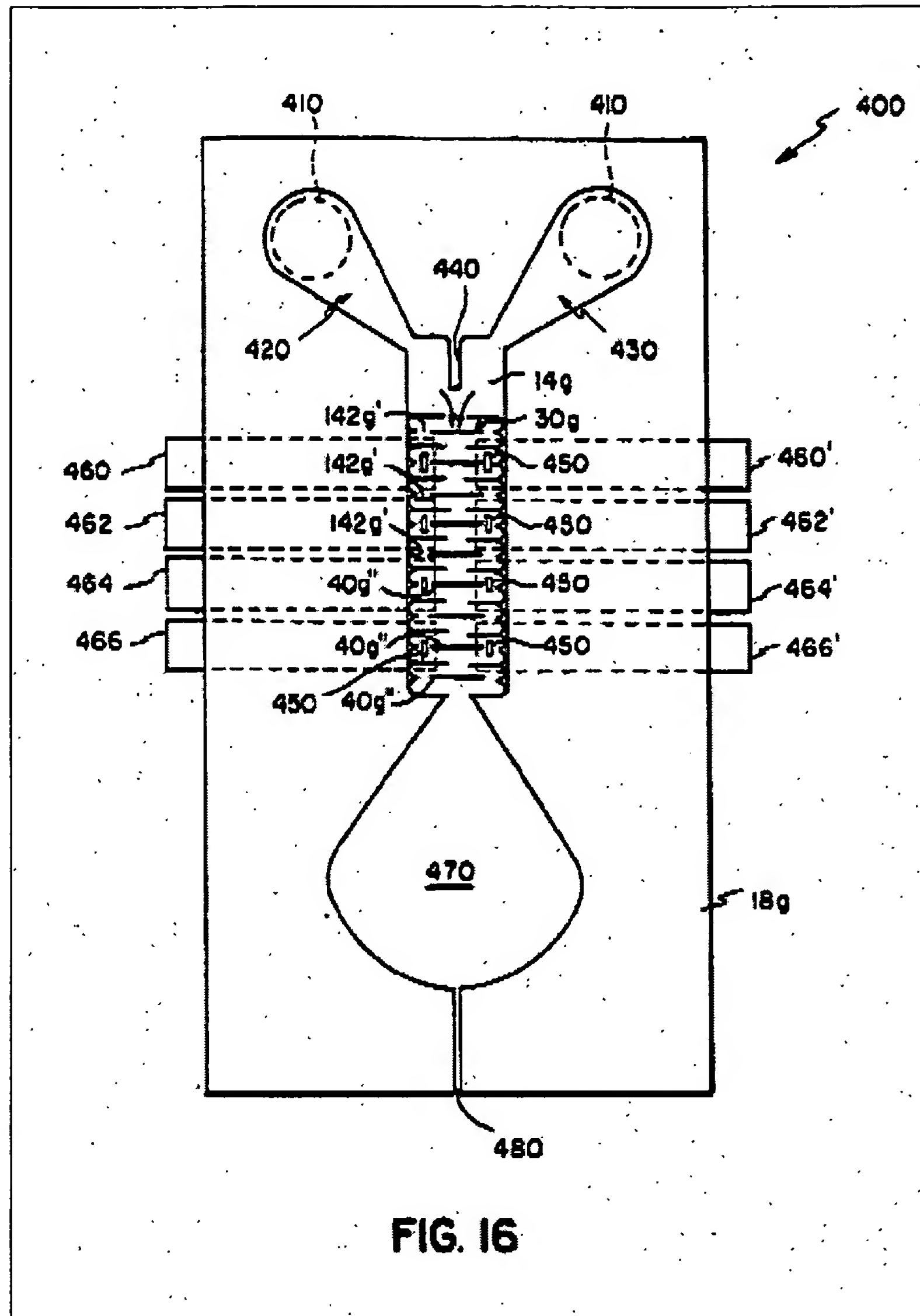


FIG. 5



Regarding claim 9, Columbus '476 teaches the incorporation of an overflow cavity or chamber (470) within the apparatus.

Regarding claim 8, the recitation that a blood anti-coagulant is deposited in the inlet chamber is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. In addition, with respect to claim

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10, the recitation that the overflow chamber contains an indicator, such as an indicator reagent, as disclosed by the applicants specification, is also considered a process or intended use limitation. The Court has held that “[e]xpressions relating the apparatus contents thereof during an intended use operation are of no significance in determining the patentability of the apparatus claim.” See *Ex parte Thilbault*, 164 USPQ 666, 667 Bd. App. 1969). Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and

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Hewlett-Packard Co. V. Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 4 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus '029 in view of Peters (U.S. Pat. No. 6,296,126 B1). Regarding claim 4, Columbus '029 is silent to the specific teaching of incorporating wedge-shaped cut-out structures with the microfluidic apparatus. As shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).

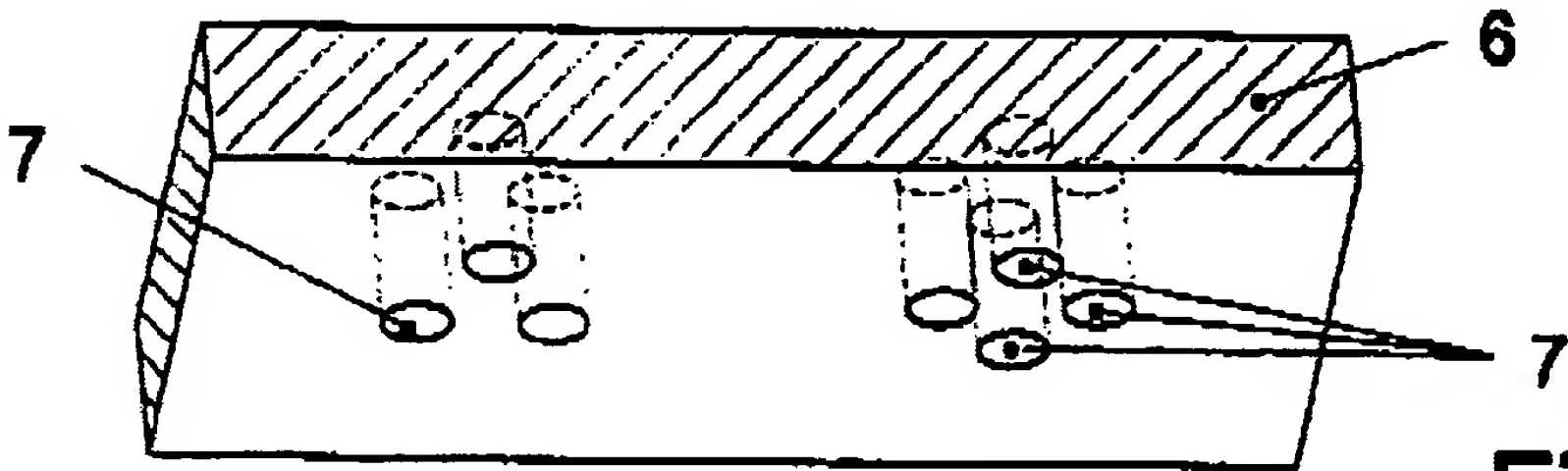


Fig. 3a

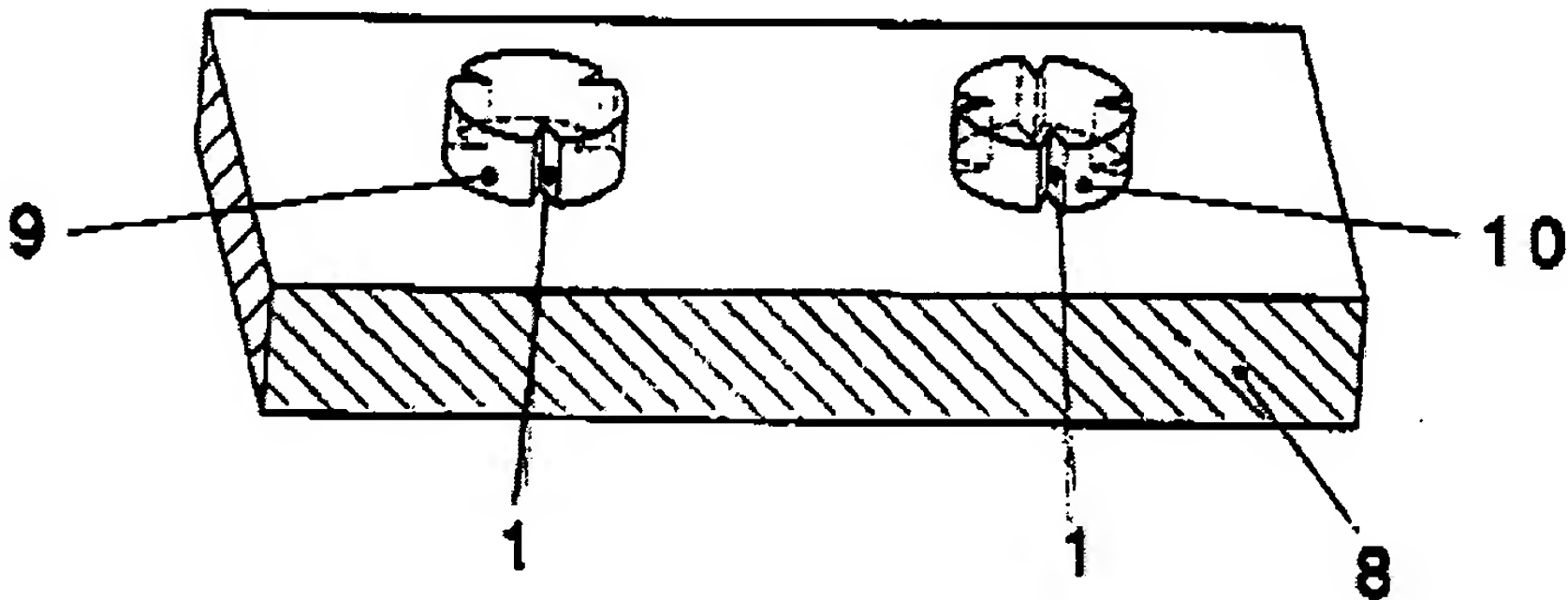


Fig. 3b

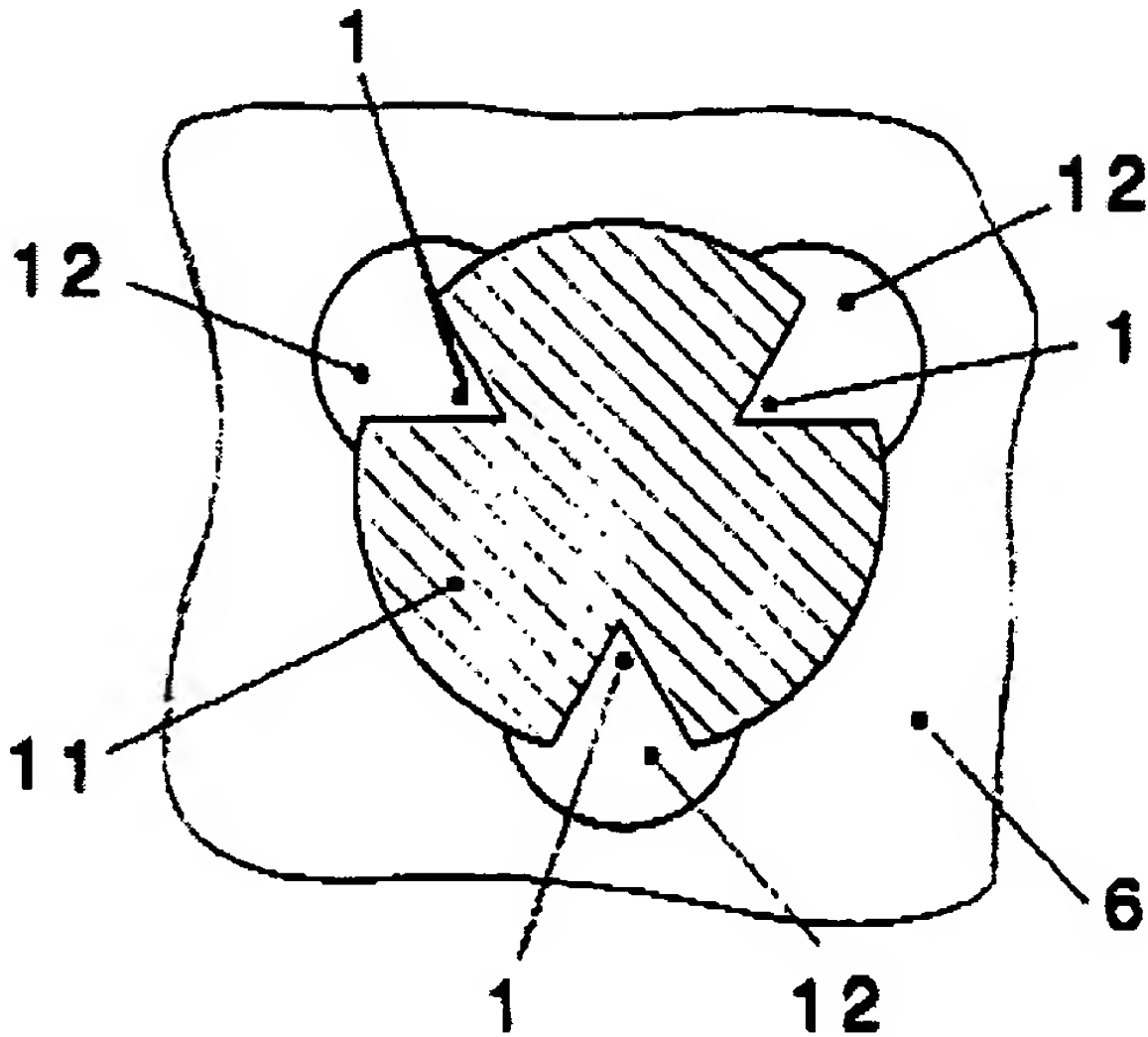


Fig. 4

As evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of wedge-shaped cut-out structures, as taught by Peters, with the microfluidic apparatus disclosed by Columbus '029 in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

Regarding claims 5 and 6, as shown in figure 3b, these cylindrical or columnar projections (9) comprise essentially post structures, which extend from the base-plate (8), having wedge-shaped cut-outs (1) (see col. 5, lines 1 – 15).

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus '029 in view of Bedingham et al. (U.S. Pat. No. 6,734,401 B2). Columbus '029 is silent to the specific teaching of incorporating an inlet port that is tapered to engage the corresponding shape of a pipette tip for depositing a sample fluid into the apparatus. Bedingham et al. do teach the incorporation of an inlet port (844') that is tapered to facilitate engagement with the corresponding shape of a pipette probe tip (849') for permitting the introduction of a sample fluid into the disclosed apparatus (see col. 32, lines 19 – 61; figure 19D).

Hence, as evidenced by Bedingham et al., a person of ordinary skill in the art would have recognized the suitability of incorporating the use of a tapered inlet port with a microfluidic apparatus for the intended purpose of facilitating effective sample fluid introduction into the microfluidic apparatus (see MPEP § 2144.07). Furthermore, in view of the teachings of Bedingham et al., a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating a tapered inlet with a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of

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success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a tapered inlet port, as taught by Bedingham et al., with the microfluidic apparatus of Columbus '029, for facilitating effective sample fluid transfer and control.

Response to Arguments

Applicant's arguments filed 3/3/2006 have been fully considered but they are not persuasive. The Applicant's arguments pertaining to how the claimed apparatus functions or operates is simply not germane to the issue of determining the patentability of the present claims that are drawn to an apparatus statutory class of invention. The recited structure of the claimed apparatus simply does not exclude the teachings of the prior art. The prior art teaches all of the positively recited structure of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian J. Sines". The signature is written in a cursive, flowing style with a large loop at the end.